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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,376	09/10/2003	Dan Nilsson	NILSSON=6B	5425

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/658,376	NILSSON, DAN	
	Examiner	Art Unit	
	Vera Afremova	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *11,27,35-37 and 39-47* is/are pending in the application.

4a) Of the above claim(s) *41-46* is/are withdrawn from consideration.

5)☒ Claim(s) *11 and 27* is/are allowed.

6)☒ Claim(s) *35,36 and 47* is/are rejected.

7)☒ Claim(s) *37, 39 and 40* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/17/2008 has been entered.

Claims 11, 27, 35-37, 39-47 as amended and newly presented are presently pending (1/17/2008).

Claims 11, 27, 35-38 have been rejected in the last office action (5/18/2007) and claims 39-47 have been newly presently after final rejection (10/16/2007 and 1/17/2008).

Election/Restrictions

Newly submitted claims 41-46 are directed to an invention(s) that is independent or distinct from the invention originally claimed for the following reasons:

New claims 41-46 are directed to a method(s) of making lactic bacteria by mutation and the other presently pending claims are directed to a product(s) with lactic bacteria. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the claimed Pfl defective lactic acid bacteria can be made by another and materially different process such as recombinant technology. In alternative, the claimed process based on

mutation of a strain can result in a materially different product(s) such as Ldh defective but PFL active bacterial strain, for example: see instant claim 46.

The invention as originally constructed and elected for prosecution (5/02/2005) is/was solely directed a pyruvate formate-lyase (PFl) defective lactic acid bacteria that is not Ldl-defective. The double defective mutant (both Pfl defective and Ldl-defective) was subject of the parent application. The election of claims drawn to a pyruvate formate-lyase (PFl) defective lactic bacterial strains such as DN221 and DN227 has been also confirmed in the after-final response (see response filed on 10/16/2007, page 6 at it. 2.4).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 41-46 are withdrawn from consideration as being directed to a non-elected invention(s). See 37 CFR 1.142(b) and MPEP § 821.03.

New claim 47, drawn to a specific strain DN225 (which is Pfl defective and Ldh active strain, see specification page 31, lines 16-18 and see also last response filed 1/17/2008 at page 7, last par.), appears to be consonant with the prior election.

Claims 11, 27, 35-37, 39, 40 and 47 are under examination in the instant office action.

Claim Objections

Claim 40 is objected to because of the following informalities:

Claims 40 appears to contain a typing error, for example: see last line of the claim 40, wherein strain DSM 11040 is belied to be intended but not strain "DSM11034" as presently written. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Deposit

1. The deposit requirement for strains *Lactococcus lactis subsp. lactis* DN221 (DSM 11034) and *Lactococcus lactis* subsp. *lactis* biovar *diacetylactis* DN227 (DSM 11040) have been met in the response papers filed 11/01/2005.

2. Claim 47 is rejected under 35 U.S.C. 112, *first paragraph,* as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At least some of the claims require one of ordinary skill in the art to have access to a specific strains *Lactococcus lactis subsp. lactis* DN225 (DSM 11038). Because the microorganism is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganisms are not so obtainable or available, the requirements of 35 U.S.C. 112 may be satisfied by deposit of the microorganism. The specification does not disclose a repeatable process to obtain the claimed specific strains because the selection method involves unpredictable effects of mutagenesis on parent culture(s). It is not particularly clear from the specification or record that the strains are readily available to the public.

The rejection may be overcome by establishing that each microorganism identified is readily available to the public and will continue to be so for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer, or by an acceptable deposit as set forth herein. See 37 CFR 1.801-1.809.

If the deposit of strains *Lactococcus lactis subsp. lactis* DN225 (DSM 11038) is made under the terms of the Budapest then an affidavit or declaration by applicants or a statement by an attorney of record over his/her signature and registration number, stating that the deposit has been made under the Budapest Treaty and that all restrictions imposed by the depositor on availability to the public of the deposited material will be irrevocably removed upon issuance of the patent would satisfy the deposit requirement. See 37 CFR 1.808.

Because DSM has acquired the status of an International Depository in accordance to the Budapest Treaty, a declaration stating that all restrictions will be irrevocably removed upon issuance of the patent will overcome this rejection.

Claim Rejections - 35 USC § 112

Indefinite

Claims 35 and 36 are rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 36 recite the Pfl defective mutant (III) or (IV) that are mutants of the Pfl defective strains DN 221 and DN 227 as claimed. The strains DN 221 and DN 227 have been deposited as DSM 11034 and DSM 11040 and at the very least their properties can be determined and/or assessed. However, the entities defined by the "mutant(s)"s (III) and (IV) are indefinite because it is unclear what "characteristics" of the parent strains DN221 and DN 227 are included into and/or excluded from the scope of the claimed subject matter as intended for the claimed invention in the lack of definitions in the as-filed specification. It remains unclear

whether the mutants III and IV are different from theirs parent stains and what will be theses differences in order to identify the claimed mutants of III and IV. The parent strain DN 227 does not have any mutants derived therefrom as disclosed and, thus, there are no definitions for the claimed mutant IV. The characterization of the claimed mutant III derived from DN221 is at the very least uncertain in view of the as-filed specification that teaches that "the defect of DN222 is unknown" (page 29, line 28) wherein DN 222 is derived from DN 221 (page 27, lines 5-12).

The claimed features from (i) to (v) relate to the characterization of the Pfl defective strains relative to a generic "wild type" as claimed. In view of specification CHCC373 and DB1341 are the parent strains ("wild-type") for the deposited strains DN 221 and DN 227 respectively. However, the terms of relative degree such as "essentially the same" "reduced" and/or "increased" rates of bacterial growth and/or various metabolite productions are not clearly defined by the claims or by specification. The specification does not provide a standard for ascertaining the requisite degree. The "wild types" as disclosed are obtained from a private collection (page 21, lines 6-10) and their features can not be assessed beyond those activities as it might be disclosed in the specification. However, the specification does not provide definitions for activities of the wild type CNCC373 under anaerobic conditions of as recited in (ii) - (v) of claims 35. Furthermore, biological activity of the "wild type" DB1341 is not described at all. Thus, the relative characterization of the claimed strains to a "wild type" strain is meaningless and, thus, indefinite, particularly for the claimed mutants III and IV which do not have any "wild type" parent for a reference as encompassed by the claims. Therefore, the metes and bounds of the claimed scope with respect to mutants III and IV can not be determined.

Claim Rejections - 35 USC § 112

New matter

Claims 35 and 36 remain rejected under 35 U.S.C. 112, *first paragraph*, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Insertion of the limitation drawn to "a mutant obtained by mutation of strain DN227" in claim 35 and the mutant (IV) in claim 36 has no support in the as-filed specification.

The insertion of this limitation is a new concept because it neither has literal support in the as-filed specification by way of generic disclosure, nor are there specific examples of the newly limited entity of a mutant IV obtained by mutation of strain DN227 that would show possession of the concept of the use of this mutated strain.

The pfl-defective mutant that is obtained by mutagenization of the strain DN227 is not described in the as-filed specification. The features for the presently claimed mutant IV are not described and, thus, unclear. The nature and effects of mutation as intended for mutant of DN 227 are not disclosed and, thus, cannot be determined. Given this lack of description of any representatives of the mutant IV encompassed by the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention, the entity of mutants derived from DN 227.

Thus, there is no sufficient support for the newly claimed entity of mutant IV. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter. Declarations and new references cannot demonstrate the possession of a concept after the fact. Thus, the insertion of limitation drawn to "a mutant obtained by mutation of strain DN227" in claim 35 and to the mutant (IV) in claim 36 is considered to be the insertion of new matter for the above reasons.

Claim Rejections - 35 USC § 112

Scope

Claims 35 and 36 are rejected under 35 U.S.C. 112, *first paragraph*, because the specification, while being enabling for the Pfl defective strains DN 221 (DSM 11034) and DN227 (DSM 11040), does not reasonably provide enablement for the mutants III and IV that are Pfl defective but not Ldl-defective and that are obtained by mutation of strains DN221 and DN227 respectively. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Nature of the invention relates to lactic bacterial starter cultures that produce increased amounts of desirable products and reduced amounts of less desirable products (page 1, lines 3-10).

Breadth of the claims is directed to a variety of some identified strains DN 221 (DSM 11034) and DN227 (DSM 11040) and some unidentified and/or generic mutants III and IV.

Amount of guidance and working examples directly relates to the Pfl defective strains DN 221 (DSM 11034) and DN227 (DSM 11040). However, the entities of claimed mutants III and IV are either indefinite (mutant III described as DN222 derived from DN221 at page 29, line 28) or not described at all (mutant IV being claimed as derived from DN227). Claims 35 and 36 recite the mutants III and IV as derived by mutation from DN 221 and 227 respectively. Although spontaneous or chemically- or UV- induced mutation is used for screening of thousands of microbial mutants and/or variants, it is well known and there is also a reasonable view that mutation is a random event and its outcome is unpredictable. With regard to the claimed mutant IV derived from DN 227 the as-filed specification fails to provide any example of a successful mutation that would lead to the mutant as encompassed by the claims. After chemically-induced mutation of the other strain DN221 about 1000 variants were selected and screened for the features as encompassed for claimed mutant III but it appears that only 2 potential lactic bacterial starter culture candidates were obtained (page 27). But one of them falls outside of the claimed scope of mutant III as being a double mutant having both Pfl and Ldh defects (DN 223 at page 28, line 14)) and the defect of the other strain (DN222) remains unknown as disclosed (page 29, line 28). Thus, there is a reasonable believe that the desired result of making the claimed mutants III and IV was not obtained by the random process of mutation.

Neither specification nor the prior art can be said to support the enablement of the claims over their breath as drawn to unidentified and generic mutants III and IV. Therefore, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Undue experimentation would be required to practice the invention as claimed due to the amount of experimentation necessary because of the limited amount of guidance and limited number of working examples in the specification, the nature of the invention, the state of the prior art, breadth of the claims and the unpredictability of the art.

As set forth in *In re Fisher*, 427 F2.d 833, 839, 166 USPQ 18, 24 (CCPA) 1970: [Section 112] requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.

In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of the enablement varies inversely with the degree of unpredictability of the factors involved. *Ex parte Humphreys*, 24 USPQ2d, 1260.

Response to Arguments

Applicant's arguments filed 10/16/2007 and 1/17/2008 have been fully considered but they are not all found persuasive.

In the claims 11 and 47 the phrase "strain having all of the characteristics" is interpreted as being an identical strain to the deposited strain. Claims are free from prior art.

Thus, claims 11 and 27 are allowed.

Claims 37, 39 and 40 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten to be solely directed to bacterium I or II.

Claim 47 is free from prior art but deposit requirement for the claimed strain DN225 has not been met.

The issue of election/restriction discussed by applicants in the response papers filed on 10/16/2007 and 1/17/2008 is/are addressed above.

With regard to the claim rejected under 35 U.S.C. 112, *second paragraph*, as being indefinite, applicants arguments (response 10/16/2007, page 8) are not found convincing since they are directed to analogy with a fermentation process while the rejected claims require characterization of the strains that is indefinite in the lack of specific definitions in the as-filed specification. The metes and bounds of the mutants III and IV also cannot be determined due to uncertainly of relative degree of characterization as claimed.

With regard to the claim rejected under 35 U.S.C. 112, *first paragraph*, (new matter) applicants arguments (response 10/16/2007, page 8) are not found convincing because given the lack of description of any representatives of the mutant IV encompassed by the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention, the entity of mutants derived from DN 227.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

April 9, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657